sAppendix P
Colorado Medical Assistance Program
Prior Authorization Procedures and Criteria and Quantity Limits
For Physicians and Pharmacists

Drugs requiring a prior authorization are listed in this document. The Prior Authorization criteria are based on FDA approved indications, CMS approved compendia, and peer-reviewed medical literature.

Prior Authorization Request (PAR) Process

- Products qualify for a 3 day emergency supply in an emergency situation. In this case, call the help desk for an override.
- Pharmacy PA forms are available by visiting: https://www.colorado.gov/hcpf/pharmacy-resources
- PA forms can be signed by anyone who has authority under Colorado law to prescribe the medication. Assistants of authorized persons cannot sign the PA form
- Physicians or assistants who are acting as the agents of the physicians can request a PA by phone
- Pharmacists from long-term-care pharmacies and infusion pharmacy must obtain a signature from someone who is authorized to prescribe drugs before they submit PA forms
- Pharmacists from long-term-care pharmacies and infusion pharmacies can request a PA by phone if specified in the criteria
- All PA's are coded online into the PA system
- Prior Authorizations can be called or faxed to the helpdesk at

  Phone: 1-800-424-5725
  Fax: 1-888-424-5881

- Non-narcotic prescriptions may be refilled after 75% of previous fill is used. Narcotic prescriptions may be refilled after 85% of the previous fill is used. Synagis may be refilled after 92.5% of the previous fill is used.

Medical Supply Items and Medications

- All supplies, including insulin needles, food supplements and diabetic supplies are not covered under the pharmacy benefit, but are covered as medical supply items through Durable Medical Equipment (DME)
- If a medical benefit requires a PA, the PA request can be submitted through the provider application available at: http://www.coloradopar.com/
- Effective March 4, 2013 all PARs and revisions processed by the Colorado PAR Program must be submitted using CWQI. After April 1, 2013, PARs submitted via fax or mail will not be entered into CWQI and subsequently not reviewed for medical necessity.
- DME questions should be directed to DXC Technology (Formerly Hewlett Packard Enterprise) 1-844-235-2387. Only policy questions regarding Durable Medical Equipment should be directed to the state at 303-866-3406.
- Medications given in a hospital, doctor's office or dialysis unit are to be billed directly by those facilities as a medical item. IV Fluids, meds, etc. may be billed by the pharmacy when given in a long-term care facility or by home infusion.
- Initiation of pharmaceutical product subject to Prior Authorization:
  - Please note that starting the requested drug, including a non-preferred drug, prior to a PA request being reviewed and approved, through either inpatient use, by using office "samples", or by any other means, does not necessitate Medicaid approval of the PA request.

Drug	Criteria	PAR Length
Drug classes that have been migrated to the Preferred Drug List (PDL) https://www.colorado.gov/hcpf/pharmacy-resources	Anticoagulants (oral), Antidepressants, Antiemetics, Antiherpetics, Antihistamines with decongestants, Antihypertensives, Antiplatelets, Atypical Antipsychotics (oral), Bisphosphonates (oral), Constipation (opioid-induced), Diabetes Management Classes, Erythropoiesis Stimulating Agents, Fibromyalgia Agents, Filgrastim/Pegfilgrastim/Sargromastim/Filgrastim-SNDZ, Fluoroquinolones, Growth Hormones, Hepatitis C Virus Treatments, Insulin, Intranasal Corticosteroids, Leukotrienes, Multiple Sclerosis Agents, Neurocognitive Disorder Agents, Ophthalmic Allergy Products, Otezla (apremilast), Overactive Bladder Agents, Pancreatic Enzymes, Proton Pump Inhibitors, Pulmonary Arterial Hypertension Therapies, Respiratory Inhalents, Sedative Hypnotics, Skeletal Muscle Relaxants, Stimulants and other ADHD Agents, Targeted Immune Modulators (self-administered), Testosterone Products, Topical Immunomodulators, Triptans	
ACETAMINOPHEN CONTAINING PRODUCTS	A prior authorization is required for dosages of acetaminophen containing products over 4000mg/day of acetaminophen. Doses over 4000mg/day are not qualified for emergency 3 day supply PA	N/A
ACNE PRODUCTS Topical Tretinoin Products and Isotretinoin Products	Prior authorization is required for all topical tretinoin and isotretinoin products. Payment for topical tretinoin therapy and isotretinoin products will be authorized for the following diagnoses: Cystic acne, disorders of Keratinization, psoriasis, neoplasms, comedonal or acne vulgaris. • *Cystic acne, disorders of Keratinization, psoriasis, or neoplasms*, do **not** require previous trials and therapy failure with other legend or non-legend anti-acne products regardless of age. Approval will be granted for a one-year period. • The diagnosis of *comedonal* does **not** require previous trial and therapy failure with other legend or non-legend anti-acne products regardless of age. Approval will be granted for an initial three-month period. IF topical tretinoin therapy is effective after the initial approval period, a prior authorization will be granted for a one-year period. • A diagnosis of *acne vulgaris* **requires** previous trials and treatment failures on antibiotic and /or topical treatments. If criteria are met, a prior authorization will be granted for a one-year period. **Quantity limit:** Duac Convenience kit is 1 unit (kit) per 30 days Aldara is 12 packets per 28 days	**See criteria**
ADOXA TT AND CK KIT	A prior authorization will only be approved if a member has tried and failed on the generic oral doxycycline or topical clindamycin for a period of 3 or more months in the last 6 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year

ALBUMIN	Must have an FDA approved indication and given in the member's home or in a long-term care facility for approval. The following are FDA approved indications:
	• Hypoproteinemia
	• Burns
	• Shock due to:
	  ○ Burns
	  ○ Trauma
	  ○ Surgery
	  ○ Infection
	• Erythrocyte resuspension
	• Acute nephrosis
	• Renal dialysis
	• Hyperbilirubinemia
	• Erythroblastosis fetalis
		One year

ALLERGY EXTRACT PRODUCTS-Oral (Grastek, Oralair, Ragwitek)	***Grastek (Timothy grass pollen allergen extract)*** Must be between 5 and 65 years old. Must not be pregnant or nursing. Must be prescribed by an allergist. Must have a documented diagnosis to ONLY timothy grass pollen allergen extract or the Pooideae family (meadow fescue, orchard, perennial rye, Kentucky blue, and red top grasses) confirmed by positive skin test or IgE antibodies. Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Must be willing to administer epinephrine in case of severe allergic reaction. Must take first dose in physician's office. Must be started 12 weeks prior to the season if giving only seasonally. May be taken daily for up to 3 consecutive years. Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat • Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis • Allergic to any of the inactive ingredients contained in Grastek which include gelatin, mannitol, and sodium hydroxide • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics. • Be taken with other immunotherapy (oral or injectable) ***Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, Kentucky Blue Grass mixed pollens allergen extract)*** Must be between 10 and 65 years old. Must not be pregnant or nursing. Must be prescribed by an allergist. Must have a documented diagnosis to ONLY Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass allergen extract confirmed by positive skin test or IgE antibodies. Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Must be willing to administer epinephrine in case of severe allergic reaction. Must take first dose in physician's office. Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat	One year

	• Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis • Allergic to any of the inactive ingredients contained in Oralair which include mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, and lactose monohydrate. • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics. • Be taken with other immunotherapy (oral or injectable) ***Ragwitek (short ragweed pollen allergen extract)*** Must be between 18 and 65 years old. Must be started 12 weeks prior to the season and only prescribed seasonally. Must not be pregnant or nursing. Must be prescribed by an allergist. Must have a documented diagnosis to ONLY short ragweed pollen allergen extract or the Ambrosia family (giant, false, and western ragweed) confirmed by positive skin test or IgE antibodies. Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Must be willing to administer epinephrine in case of a severe allergic reaction. Must take first dose in physician's office. Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat • Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis • Allergic to any of the inactive ingredients contained in Ragwitek which include gelatin, mannitol, and sodium hydroxide • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics. • Be taken with other immunotherapy (oral or injectable)	
ALPHA –1 PROTEINASE INHIBITORS **Aralast, Prolastin and Zemaira**	FDA approved indication if given in the member's home or in a long-term care facility: • Aralast: Chronic augmentation therapy in members having congenital deficiency of Alpha –1 Proteinase Inhibitor with clinically evident emphysema • Prolastin: Emphysema associated with Alpha-1 Antitrypsin Deficiency	Lifetime

	• Zemaira: Chronic augmentation and maintenance therapy in members with Alpha- 1 Proteinase Inhibitor deficiency with clinically evident emphysema	
ANOREXIENTS (Diet Pills)	Belviq (lorcaserin) Contrave (naltrexone/bupropion) Qsymia (phentermine/topiramate ER) Saxenda (liraglutide) Xenical (Orlistat)	Weight loss drugs are not a covered benefit.
ANTI-ANEMIA DRUGS (Oral and injectable drugs)	FDA approved indication: Iron Deficiency Anemia Injectable Drugs [i.e.: Infed (iron dextran), Venofer, Ferrlecit] • Diagnosis of iron deficiency anemia when oral preparations are ineffective or cannot be used. Must be administered in a member's home or in a long-term care facility.	Lifetime
ATYPICAL ANTIPSYCHOTICS (Injectable) Abilify Maintena, Invega Sustenna, Geodon and Risperdal Consta, Zyprexa Relprevv	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility or in a member's home. Oral atypical antipsychotic criteria can be found on the Preferred Drug List.	One year
BACTROBAN (mupirocin) Nasal Cream and Ointment (Generic Bactroban Ointment does not require a prior authorization)	**Bactroban Cream** (mupirocin calcium cream) must be prescribed for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm^2 in total area), impetigo, infected eczema or folliculitis caused by susceptible strains of Staphylococcus aureus and Streptococcus pyogenes. **Bactroban Nasal Ointment** (mupirocin calcium) must be prescribed for the eradication of nasal colonization with methicillin-resistant Staphylococcus aureus in adult patients and health care workers as part of a comprehensive infection control program to reduce the risk of infection among patients at high risk of methicillin-resistant S. aureus infection during institutional outbreaks of infections with this pathogen.	Cream: One year Nasal Ointment: Lifetime
BARBITURATES Medicare-Medicaid enrollees	Barbiturates will require prior authorization for all Medicaid members. Beginning on January 1, 2013, the Colorado Medicaid Program will no longer be allowed to cover barbiturates for Medicare-Medicaid enrollees (dual-eligible members).For Medicaid primary members, barbiturates will be approved for use in epilepsy, cancer, chronic mental health disorder, sedation, treatment of insomnia, tension headache, muscle contraction headache and treatment of raised intracranial pressure. All other uses will require manual review. For Phenobarbital see the section titled Phenobarbital.	One year
BENLYSTA (belimumab)	A prior authorization may be approved only when documentation has been received indicating that the drug is being administered in the member's home or long-term care facility. The member must also meet the following criteria: • Diagnosis of autoantibody positive SLE with organ involvement; AND • Incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids; AND • Maintenance of standard therapy while on BENLYSTA.	One year
BENZODIAZEPINES Medicare-Medicaid enrollees	Benzodiazepines will no longer be a Medicaid benefit for Medicare-Medicaid enrollees (dual-eligible members). The claims are no longer excluded from Medicare part D coverage, and thus must be billed to Medicare part D. The Colorado Medicaid Program will no longer be allowed to cover these medications beginning on January 1, 2013. Coverage will remain in effect for Medicaid primary members.	One year
BONE RESORPTION SUPPRESSION AND	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility or in a member's home.	One year

RELATED AGENTS (Injectable formulations) Didronel, Boniva, Aredia, Miacalcin, Zemplar, Hectorol, Zometa, Reclast, Pamidronate, and Ganite	Prolia (denosumab) will be approved if the member Meets the following criteria: • Member is in a long term care facility or home health (this medication is required to be administered by a healthcare professional) AND • Member has one of the following diagnoses: o Postmenopausal osteoporosis with high fracture risk o Osteoporosis o Bone loss in men receiving androgen deprivation therapy in prostate cancer o Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer AND • Member has serum calcium greater than 8.5mg/dL AND • Member is taking calcium 1000 mg daily and at least 400 IU vitamin D daily AND • Has trial and failure of preferred bisphosphonate for one year AND (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) • Member meets ANY of the following criteria: o has a history of an osteoporotic vertebral or hip fracture o has a pre-treatment T-score of < -2.5 o has a pre-treatment T-score of < -1 but > -2.5 AND either of the following: • Pre-treatment FRAX score of > 20% for any major fracture • Pre-treatment FRAX score of > 3% for hip fracture Maximum dose of Prolia is 60mg every 6 months	
BLOOD PRODUCTS	FDA approved indications if given in the member's home or in a long-term care facility: • Plasma protein fraction; shock due to burns, trauma, surgery; hypoproteinemia; adult respiratory distress syndrome; cardiopulmonary bypass; liver failure; renal dialysis; or hemophilia.	Lifetime
BOTULINUM TOXIN	Botox, Myobloc, Xeomin, Dysport If given in the member's home or in a long-term care facility. • *Cervical or Facial Dystonia* ***Not approved for Cosmetic Purposes***	One year
BOWEL PREPERATION AGENTS	For the following Bowel Preparation Agents, members will require a prior authorization for quantities greater than 2 units per month. • Colyte • Gavilyte-C • Gavilyte-H • Gavilyte-N • Gialax • Golytely • Moviprep • Peg-Prep • Trilyte	30 days
BRAND NAME MEDICATIONS	Only brand name drugs that have a generically equivalent drug (as determined by the FDA) require a prior authorization. Exceptions to the rule include: • The brand name drug has been exempted (see the list below) • When the reimbursement for a brand-name drug is less expensive than the cost of the generic equivalent	One year

	• **The physician is of an opinion that a transition to the generic equivalent of a brand-name drug would be unacceptably disruptive to the patient's stabilized drug regimen** • **The patient is started on a generic drug but is unable to continue treatment on the generic drug as determined by the patient's physician** The following list of drug classes is exempt from the generic mandate rule (no PA is required). Medications used for the treatment of: • Biologically based mental illness defined in 10-16-104 (5.5) C.R.S. • Cancer • Epilepsy • HIV/AIDS	
BUTALBITAL-CONTAINING PRODUCTS Quantity limits	Effective August 1, 2014, products containing butalbital are limited to 180 units in 30 days. For members receiving more than 180 tablets in 30 days, these claims will be escalated to the Department for individual review. Please note that if more than one agent is used, the combined total utilization may not exceed 180 units in 30 days.	Case by case
CERDELGA (eligulstat)	Cerdela will be approved if all the following criteria are met: • Member has a diagnosis of Gaucher disease type 1 **AND** • Documentation has been provided to the Department that the member is a CYP2D6 extensive, intermediate, or poor metabolizer as detected by an FDA cleared test **AND** • Members who are CYP2D6 intermediate or poor metabolizers are not taking a strong CYP3A inhibitor (e.g, indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole, itraconazole, ketoconazole, nefazodone) **AND** • Members who are CYP2D6 extensive or intermediate metabolizers are not receiving strong or moderate CYP2D6 inhibitors (e.g, sertraline, duloxetine, quinidine, paroxetine, fluoxetine, buproprion, terbinafine) **AND** a strong or moderate CYP3A inhibitor (e.g, indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole, itraconazole, ketoconazole, fluconazole, nefazodone, verapamil, diltiazem) Quantity Limits: Max 60 tablets/30 days	One year
CHOLBAM (cholic Acid)	**CHOLBAM**® capsules will be approved for members who meet the following criteria: • Bile acid synthesis disorders: o Member must be greater than 3 weeks old in age AND o Member has a diagnosis for bile acid synthesis disorder due to single enzyme defect (Single Enzyme-Defect Disorders: Defective sterol nucleus synthesis, 3β-hydroxy-Δ-c27-steroid oxidoreductase deficiency, AKR1D1 deficiency, CYP7A1 deficiency, Defective side-chain synthesis, CYP27A1 deficiency (cerebrotendinous xanthomatosis), 2-methylacyl-CoA racemase deficiency (AMACR), 25-hydroxylation pathway (Smith–Lemli-Opitz). • Peroxisomal disorder including Zellweger spectrum disorders: o Member must be greater than 3 weeks old in age AND o Member has diagnosis of peroxisomal disorders (PDs) including Zellweger spectrum disorders AND o Member has manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption.	One year
CIALIS (tadalafil)	Cialis will be approved for members with a documented diagnosis of BPH who have failed a trial of finasteride (at least 3 months in duration) AND either a trial of a nonselective alpha blocker (therapeutic dose for at least two months) OR a trial of tamsulosin (therapeutic dose for at least one month). Documentation of BPH diagnosis will require BOTH of the following:	One year

<table>
<tr><td></td><td>• AUA Prostate Symptom Score ≥ 8 AND
• Results of a digital rectal exam.
Cialis will not be approved for any patient continuing alpha-blocker therapy as this combination is contraindicated in this population.
Doses exceeding 5mg per day of Cialis will not be approved.</td><td></td></tr>
<tr><td>CITALOPRAM (high dose)</td><td>Prior authorization will be required for doses exceeding 40mg/day. Please see the FDA guidance at: https://www.fda.gov/drugs/drugsafety/ucm297391.htm for important safety information.</td><td>One year</td></tr>
<tr><td>COLCRYS (colchicine)</td><td>Quantity Limits:
• Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days
• Familial Mediterranean Fever:120 tablets per 30 days</td><td>One year</td></tr>
<tr><td>COUGH AND COLD (Rx)</td><td>Member <21 years: covered benefit. A prior authorization is not needed.
Member ≥ 21 years must have diagnosis of a chronic condition such as COPD or asthma.</td><td>One year</td></tr>
<tr><td>COX-2 INHIBITORS

Celebrex (celecoxib) brand and generic</td><td>PA is required for members who are 64 years of age and younger. Members over the age of 65 do not require a PA.
A PA will be approved if the COX-2 is prescribed for a FDA approved indication.
<table>
<tr><th>FDA Approved Indication</th><th>Dose and Length of PA</th></tr>
<tr><td>Acute Pain</td><td>Up to 600mg day 1; 200mg BID for no more than 30 days</td></tr>
<tr><td>Dysmenorrhea</td><td>Up to 600mg day 1; 200mg BID. One year approval</td></tr>
<tr><td>Ankylosing spondylitis</td><td>200mg daily; after 6 weeks of 200mg daily dosing if member's condition has been unresponsive, 400mg daily may be approved. Lifetime approval</td></tr>
<tr><td>Familial Adenomatous Polyposis</td><td>400mg BID. Lifetime approval</td></tr>
<tr><td>Osteoarthritis</td><td>200mg daily; 100mg BID. Lifetime approval</td></tr>
<tr><td>Rheumatoid Arthritis</td><td>100-200mg BID. Lifetime approval</td></tr>
<tr><td>Juvenile Rheumatoid Arthritis</td><td>Up to 100mg BID. 6 month approval</td></tr>
</table></td><td>See chart</td></tr>
<tr><td>DALIRESP (roflumilast)</td><td>DALIRESP® tablets will be approved for members that meet the following criteria:
• Member has a diagnosis for severe COPD with history of COPD exacerbations (2 or more per year) and chronic bronchitis AND
• Member must be greater than 18 years of age AND
• Member must have failed a trial of two of the following: long-acting beta2 agonist, preferred anticholinergic/anticholinergic combination, or preferred inhaled anticholinergic/anticholinergic combinations due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction AND
• Member must not have moderate to severe liver disease (Child Pugh B or C).

Note: this medication is not a bronchodilator and cannot be used for acute bronchospasms</td><td>One year</td></tr>
<tr><td>DARAPRIM (pyrimethamine)</td><td>Prior Authorization required and will be reviewed on a case by case basis, based on medical necessity</td><td></td></tr>
<tr><td>DESI DRUGS</td><td>DESI drugs (Drugs designated by the Food and Drug Administration as Less Than Effective Drug Efficacy Study Implementation medications) are not a covered benefit.</td><td>None</td></tr>
<tr><td>DIFICID (fidoxomicin)</td><td>Dificid will be approved if all the following criteria are met:</td><td>10 days</td></tr>
</table>

	• The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient's medical records AND • Prescriber must be a gastroenterologist or an infectious disease specialist AND • Diagnosed with Clostridium difficile-associated diarrhea AND • ≥ 18years of age AND • Failed at least a 10 day treatment course with oral metronidazole AND oral vancomycin OR • Allergy and/or intolerance to both metronidazole and vancomycin Quantity limits: Dificid: Max 20 tabs/30 days	
DUEXIS (famotidine/ibuprofen)	Duexis will be approved for members that meet the following criteria: • Member has a diagnosis of rheumatoid arthritis or osteoarthritis AND • Member has failed a trial of an NSAID taken with three preferred proton pump inhibitors (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year
DUPIXENT (dupilumab)	DUPIXANT will be approved if all the following criteria have been met: • Member is 18 years and older AND • Member has a diagnosis of severe chronic atopic dermatitis AND • Member has a history of failure, contraindication, or intolerance to both of the following: o One medium potency to very-high potency topical corticosteroid [e.g.,Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)] AND o One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] AND • For members under 18 years of age, must be prescribed by or in conjunction with a dermatologist • Quantity limit of 2 syringes every 28 days after initial 14 days of therapy (first dose is twice the regular scheduled dose)	One Year
EGRIFTA® (tesamorelin acetate)	Prior Authorization required and will be approved on a case by case basis The Drug Utilization Review (DUR) will be reviewing criteria	
ELESTRIN GEL (estradiol)	A prior authorization will only be approved if a member has tried and failed on generic oral estradiol therapy and diagnosed with moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year
EMFLAZA (deflazacort)	EMFLAZA may be approved if all the following criteria are met: • Member is at least 5 years of age or older AND • Member has diagnosis of Duchenne muscular dystrophy and a documented mutation in the dystrophin gene AND • Member must have documented (per claims history or provider notes) adequate trial and/or failure to prednisone therapy, adequate trial duration is at least three month. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) AND • The medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders. AND • Serum creatinine kinase activity at least 10 times the upper limit of normal at some stage in their illness AND • Absence of active infection including tuberculosis and hepatitis B virus	One year

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<tr><td></td><td>
Maximum dose of 0.9mg/kg daily for tablets and suspension, may be rounded up to nearest ml
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<tr><td>EMVERM (mebendazole)</td><td>
Emverm will be approved for members that meet the following criteria:

Member is 2 years or older AND
Member has a diagnosis of one of the following: Ancylostoma duodenale or Necator americanus (hookworm), Ascariasis (roundworm), Enterobiasis (pinworm), or Trichuriasis (whipworm) AND
Member has failed a trial of albendazole for FDA approved indication and duration (Table 1) (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) AND

<table>
<tr><th>Diagnosis</th><th>Dose</th><th>Duration</th><th>Quantity Limits</th></tr>
<tr><td>Ancylostoma duodenale or Necator americanus (hookworm)</td><td>100 mg twice daily</td><td>3 consecutive days, may be repeated in 3 weeks in needed.</td><td>6 tablets/member</td></tr>
<tr><td>Ascariasis (roundworm)</td><td>100 mg twice daily</td><td>3 consecutive days, may be repeated in 3 weeks if needed.</td><td>6 tablets/member</td></tr>
<tr><td>Enterobiasis (pinworm)</td><td>100 mg once</td><td>May give second dose in three weeks if needed.</td><td>2 tablets/member</td></tr>
<tr><td>Trichuriasis (whipworm)</td><td>100 mg twice daily</td><td>3 consecutive days, may be repeated in 3 weeks in needed.</td><td>6 tablets/member</td></tr>
</table>

For diagnoses other than pinworm, Emverm is being prescribed by an infectious disease specialist AND
Female members have a negative pregnancy test AND
Emverm Is being prescribed in accordance to FDA dosing and duration (Table 1)

Quantity limits will be based on indication (Table 1)

Table 1. Emverm FDA Approved Dosing and Duration in Adults and Children.
</td><td>See Table</td></tr>
<tr><td>ENTRESTO (sacubitril/valsartan)</td><td>
ENTRESTO will be approved for members if the following criteria has been met:

Member has a diagnosis of heart failure with reduced ejection fraction and NYHA Class II to IV AND
Member is NOT currently on ACE-inhibitor or Angiotensin Receptor Blocking agent AND
Member does not have history of angioedema related to previous ACE inhibitor or ARB therapy

</td><td>One year</td></tr>
<tr><td>EPANED (enalapril)</td><td>Epaned will be approved for members under the age of 5 years who cannot swallow a whole or crushed tablet.</td><td>One year</td></tr>
</table>

SEXUAL OR ERECTILE DYSFUNCTION (SD/ED) DRUGS Caverject Cialis Edex Levitra Muse Viagra Addyi Osphena Premarin Cream Xiaflex	These drugs are not a covered benefit for SD/ED indications. Yohimbine: PAs can no longer be approved for erectile dysfunction. Any PAs for use as a mydriatic agent or a vasodilator (not related to erectile dysfunction) may be approved.	Not available Not qualified for emergency 3 day supply
ESBRIET (Pirenidone)	Esbriet will be approved if all the following criteria are met: • Member has been diagnosed with idiopathic pulmonary fibrosis AND • Is being prescribed by or in conjunction with a pulmonologist AND • Member is 18 years or older AND • Member has baseline ALT, AST, and bilirubin prior to starting therapy AND • Member does not have severe (Child Pugh C) hepatic impairment, severe renal impairment (Crcl<30 ml/min), or end stage renal disease requiring dialysis AND • Female members of reproductive potential must have been counseled regarding risk to the fetus AND • Member is not receiving a strong CYP1A2 inducer (e.g, carbamazepine, phenytoin, rifampin)	One year
EUCRISA (crisaborole)	EUCRISA will be approved if all the following criteria are met: • Member is at least 2 years of age and older AND • Member has a diagnosis of mild to moderate atopic dermatitis AND • Member has a history of failure, contraindication, or intolerance to at least two medium- to high-potency topical corticosteroid for a minimum of 2 weeks, or is not a candidate for topical corticosteroids AND • Member must have trialed and/or failed pimecrolimus and tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions. AND • Must be prescribed by or in conjunction with a dermatologist	One year
FENTANYL PREPARATIONS Short acting Actiq, Fentora, Onsolis, Subsys Long acting Duragesic Transdermal System	Actiq, Fentora, Onsolis and Subsys: Approval will be granted for members experiencing breakthrough cancer pain and those that have already received and are tolerant to opioid drugs for the cancer pain AND are currently being treated with a long-acting opioid drug. The PA may be granted for up to 4 doses per day. Fentanyl patches will require a PA for doses of more than 15 patches/30 days (taking one strength) or 30 patches for 30 days (taking two strengths). For fentanyl patch strengths of 37mcg/hr, 62mcg/hr, and 87mcg/hr. Member must trial and fail two preferred strengths of separate patches summing desired dose (i.e. 12mcg/hr + 50mcg/hr =62mcg/hr) For all Fentanyl preparations: If the patient is in hospice or palliative care, the PA will be automatically granted regardless of the number of doses prescribed.	One year
FERRIPROX (Deferiprone)	Prior Authorization required and will be approved on a case by case basis The Drug Utilization Review (DUR) will be reviewing criteria	
FLECTOR 1.3% PATCH (diclofenac)	A prior authorization will only be approved if a member has tried and failed on Voltaren Gel. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year

FLUORIDE PREPARATIONS	A prior authorization will not be needed for members less than 21 years of age. For members 21 years old or older, approval will be granted if using well water or otherwise living in an under fluorinated area according to the CDC at: https://nccd.cdc.gov/DOH_MWF/Default/CountyList.aspx?state=Colorado&stateid=8&stateabbr=CO&reportLevel=2. Other situations will require a letter of necessity and will be individually reviewed.	One year
FLUOROQUINOLONES	This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at https://www.colorado.gov/hcpf/provider-forms for the Preferred Products.	One year
FUZEON (enfuvirtide)	If administered in the physician's office or delivered to physician's office, physician must bill as a medical claim on the 1500 claim form **(no PA required).** If administered in the member's home or in a long-term care facility, a prior authorization is required and must meet the criteria below for approval Based on clinical trial data, ENF should be used as part of an *optimized* background regimen for treatment-experienced members: • For treatment-experienced members with evidence of HIV-1 replication, treatment should include at least one antiretroviral agent with demonstrated HIV-1 susceptibility on the basis of genotypic/phenotypic *resistance* assays, and *two* "active" antiretroviral agents. ○ Members must have limited treatment options among currently commercially available agents. • Members must be 18 years of age or older with advanced HIV-1 infection, and not responding to approved antiretroviral therapy. • Members must have a CD4 lymphocyte count less than 100 cells/mm3 and a viral load greater than 10,000 copies/ml (measurement within the last 90 days). Past adherence must be demonstrated based on: • Attendance at scheduled appointments, and/or • Prior antiretroviral regimen adherence, and/or • Utilization data from pharmacy showing member's use of medications as prescribed • Ability to reconstitute and self-administer ENF therapy. At 24 weeks, members must experience at least ≥ 1 $\log_{10}$ decrease in HIV RNA or have HIV RNA below quantifiable limits to continue treatment with ENF. Members are not eligible if antiretroviral treatment-naive and/or infected with HIV-2. Pre-approval is necessary Practitioner must either be Board Certified in Infectious Disease, or be an HIV experienced practitioner. Verification must be produced with the prior approval documents. **These guidelines may be modified on the basis of other payer formularies and/or the emergence of new data.**	Six months
GATTEX (teduglutide)	Prior authorization will be approved if all of the following criteria are met: • Member is 18 years of age or older; • Member has documented short bowel syndrome; • Member is dependent on parenteral nutrition for twelve consecutive months; • The prescribing physician is a gastroenterologist; and	Two months initially; may be approved by State

	• Medical necessity documentation has been received and approved by Colorado Medicaid clinical staff (please fax to 303-866-3590 attn: Clinical Pharmacy Staff) • The initial prior authorization will be limited to a two month supply.	for up to one year
H2 BLOCKERS **Ranitidine capsules and liquid**	**Generic H2 Blockers** do not require a PA except for ranitidine capsules and liquid. Ranitidine capsules: Require the prescribing provider to certify that capsules are "medically necessary" and that the member cannot use the tablets. Ranitidine liquid: A prior authorization will be granted for members with a feeding tube or who have difficulty swallowing. A prior authorization is not required for children under 12 years of age.	One year
HETLIOZ (tasimelteon)	**HETLIOZ®** will be approved for members who meet the following criteria: • Have a documented diagnosis of non-24-hour sleep wake disorder (non-24 or N24) by a sleep specialist AND • Member is completely blind	One year
Homozygous Familial Hypercholesterolemia (HoFH)	**Juxtapid (lomitapide)** Prior authorization will be approved if all of the following criteria are met: • Member is 18 years of age or older; • Member has documented diagnosis of homozygous familial hypercholesterolemia (HoFH); • Member has failed therapy with high dose statin therapy (e.g. atorvastatin 40mg or higher, Crestor 20mg or higher) • The prescribing physician is enrolled in the Juxtapid REMS program. **Kynamro (mipomersen)** will be approved for members meeting all of the following criteria: • Confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by either a or b a. Laboratory tests confirming diagnosis of HoFH: LDLR DNA Sequence Analysis OR LDLR Deletion/Duplication Analysis for large gene rearrangement testing---only if the Sequence Analysis is negative OR APOB and dPCSK9 testing if both of the above tests are negative but a strong clinical picture exists. b. Documentation is received confirming a clinical or laboratory diagnosis of HoFH • Has a history of therapeutic failure, contraindication, or intolerance to high dose statin therapy or cholesterol absorption inhibitor (ezetimibe or bile acid resin) AND • Is being prescribed by a physician specializing in metabolic lipid disorders AND • The prescriber is enrolled in the REMS program AND • Is not being used as monotherapy AND • Has baseline liver function (AST,ALT, ALK,, and total bilirubin) AND • Does not have moderate or severe hepatic impairment or active liver disease.	One year
HORIZANT (gabapentil enacarbil)	**HORIZANT®** will be approved for members who have a diagnosis of Restless Leg Syndrome and who meet the following criteria: • Member has failed a one month trial of Mirapex® (pramipexole) and Requip® (ropinorole) AND • Member has had a positive therapeutic response to generic gabapentin but incomplete response due to duration of action. Max quantity: 30 tablets/30 days **HORIZANT®** will be approved for members who have a diagnosis of Post Herpetic Neuralgia and who meet the following criteria:	One year

<table>
<tr><td></td><td>• Member has failed a one month trial of tricyclic antidepressant, pregabalin and gabapentin

Max quantity: 60 tablets / 30 days</td><td></td></tr>
<tr><td>HORMONE THERAPY</td><td>Depo Provera (medroxyprogesterone)/ Lunelle (estradiol cipionate/medroxyprogesterone)
FDA approved indication if given in a long-term care facility or in the members home:
• Females: Contraception, uterine bleeding, amenorrhea, endometrial cancer
• Males: Sexual aggression / Pedophilia – Only Depo-Provera will be approved
• Not approved for administration in the physician’s office – these must be billed through medical.
Implanon (etonogestrel)
See PHYSICIAN ADMINISTERED DRUGS. Not a covered pharmacy benefit when implanted in the clinic or hospital outpatient center.
Nexplanon (etonogestrel)
• See PHYSICIAN ADMINISTERED DRUGS. Not a covered pharmacy benefit when implanted in the clinic or hospital outpatient center.</td><td>One year</td></tr>
<tr><td>HP ACTHAR (corticotropin)</td><td>HP Acthar will be approved for members that meet the following criteria:
• Member has a diagnosis of Infantile Spasms (West Syndrome) and meets all the criteria below:
o Member is < 2 years of age
o Member has electroencephalogram documenting diagnosis
o Acthar is being used as monotherapy
o Member does not have suspected congenital infection
o Prescribed by or in consultation with a neurologist or epileptologist
AND
• Member does not have concomitant primary adrenocortical insufficiency or adrenocortical hyperfunction AND
• Member is not receiving concomitant live or live attenuated vaccines AND
• Member does not have one of the following concomitant diagnoses:
o Scleroderma, osteoporosis, systemic fungal infections, ocular, herpes simplex, recent surgery, history of or the presence of a peptic ulcer, heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin. AND
• HP Acthar will be approved based on the following FDA recommended doses. (see Table 1)

Table 1. FDA Recommended Dosing for HP Acthar
<table><tr><th>Diagnosis</th><th>Dose</th></tr><tr><td>Infantile Spasms under Age of 2 years</td><td>75 units/m^2 IM twice daily for two weeks; After two weeks, dose should be tapered according to the following schedule: 30 U/m^2 IM in the morning for 3 days; 15 units/m^2 IM in the morning for 3 days; 10 units/m^2 IM in the morning for 3 days; and 10 units/m^2 IM every other morning for 6 days (3 doses).</td></tr></table>
Quantity Limits: 4 week supply</td><td>4 week supply</td></tr>
<tr><td>HUNTINGTONS CHOREA AGENTS</td><td>AUSTEDO (deutetrabenazine) will be approved if all the following criteria have been met:</td><td>One year</td></tr>
</table>

	• Member is 18 years and older with chorea secondary to Huntington's Disease AND • Member must have trialed and/or failed tetrabenazine, adequate trial duration is 1 month (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) AND • Member does not have a history of suicide or untreated depression AND • Member has been informed of the risks of depression and suicidality AND • Member does not have severe hepatic impairment • Maximum dose 48mg/day, 120 tablets per month TETRABENAZINE will be approved if all the following criteria have been met: • Member is 18 years and older with chorea secondary to Huntington's Disease AND • Member does not have a history of suicide or untreated depression AND • Member has been informed of the risks of depression and suicidality AND • Member does not have severe hepatic impairment • Maximum dose 50mg/day, 60 tablets per month	
INGREZZA (valbenazine)	INGREZZA will be approved if all the following criteria have been met: • Member is 18 years or older AND • Member has been diagnosed with tardive dyskinesia clinically AND • Has a baseline Abnormal Involuntary Movement Scale (AIMS) AND • If there is no improvement at 6 weeks of therapy per AIMS, the medication will be discontinued • Quantity limit of 60 capsules per 30 days	One year
IVIG	Members must have one of the following conditions: • <u>Immunodeficiency disorders:</u> o Common Variable Immunodeficiency (CVID) o Severe Combined Immunodeficiency (SCID) o X-Linked Agammaglobulinemia o X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency o Wiskott-Aldrich Syndrome o Pediatric Human Immunodeficiency Virus (HIV): ▪ Members are less than 13 years of age and CD-4 Count is > 200/mm3 • <u>Neurological disorders:</u> o Guillain-Barre' Syndrome o Relapsing-Remitting Multiple Sclerosis o Chronic Inflammatory Demyelinating Polyneuropathy o Myasthenia Gravis o Polymyositis and Dermatomyositis • <u>Chronic Lymphocytic Leukemia (CLL)</u> • <u>Autoimmune Neutropenia (AN):</u> o Absolute neutrophil count is less than 800 mm AND o Has recurrent bacterial infections • <u>Autoimmune Hemolytic Anemia (AHA)</u> • <u>Liver or Intestinal Transplant</u> • <u>Idiopathic Thrombocytopenic Purpura (ITP):</u>	One year One year CLL: One year AN: 6 months AHA: 5 weeks ITP: 5 days

	○ Preoperatively for members undergoing elective splenectomy with platelet count < 20,000 ○ Members with active bleeding & platelet count <30,000. ○ Pregnant women with platelet counts <10,000 in the third trimester. ○ Pregnant women with platelet count 10,000 to 30,000 who are bleeding.	
JADENU and EXJADE (Deferasirox)	Prior Authorization required and will be approved on a case by case basis The Drug Utilization Review (DUR) will be reviewing criteria	
KALYDECO (ivacaftor)	Kalydeco will only be approved if all of the following criteria are met: • Member has been diagnosed with cystic fibrosis AND • Member is an adult or pediatric patient 2 years of age or older AND • Documentation has been provided to indicate one of the following gene mutation: in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P,S549N, R117H, S549R or another FDA approved gene mutation.* AND • Documentation has been provided that baseline ALT and AST have been accessed and are within 2x normal limits (AST and ALT should be examined every 3 months for the first year and annually after that). * If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. Kalydeco will only be approved at doses no more than 150 mg twice daily. Prior Authorizations need to be obtained yearly. Kalydeco will not be approved for members who are concurrently receiving rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's Wort.	One year
KUVAN (sapropterin dihydrochloride)	KUVAN will be approved if all the following criteria are met: • Member is > 1 month old AND • Member has been diagnosed with hyperphenylalaninemia due to tetrahydrobiopterin responsive phenylketonuria AND • Prescriber is a metabolic specialist AND • Phenylalanine levels must be greater than 6 mg/dL for neonates through 12 years of age OR • Phenylalanine levels must be greater than 10 mg/dL for members between 13 to 17 OR • Phenylalanine levels must be greater than 15 mg/dL for members 18 years and older AND • Must be in conjunction with dietary restriction of phenylalanine • Initial approval will be for 1 month. Authorization may be extended if: ○ Members on the 10mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month of treatment should increase to 20mg/kg/day. These members will be approved for another 1 month trial at the higher dose. ○ Members on the 20mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month are considered non-responders, and treatment will be discontinued. ○ Members responding to therapy receive additional authorization at 1-year intervals.	Initial approval one month
LHRH/GnRH Luteinizing Hormone Releasing	Must be given in the member's home or in a long-term care facility. Prior authorization will be granted for FDA Approved Indications Only: • **Eligard:** Palliative-treatment of Advanced Prostate Cancer	One year

Hormone/Gonadtropin Releasing Hormone	• **Lupron (leuprolide):** Prostate Cancer, Endometriosis, Uterine Leiomyomata (fibroids), Precocious Puberty Lupron will be approved for Gender Identity Dysphoria based on the following criteria: o The member has a diagnosis of Gender Identity Dysphoria which is made by a mental health professional with experience in treating gender dysphoria. Where available, the mental health professional should ideally have training in child and adolescent developmental psychology AND o The member should have at least 6 months of counseling and psychometric testing for gender identity prior to initiation of Lupron AND o The prescribing provider has training in puberty suppression using a gonadotropin releasing hormone agonist AND o Lupron may not be started until girls and boys exhibit physical changes of puberty (confirmed by levels of estradiol and testosterone, respectively) and no earlier than Tanner stages 2-3 (bilateral breast budding or doubling to tripling testicular size to 4-8 cc). o Duration of treatment: Lupron will be covered to a maximum of 16 years of age for Gender Identity Dysphoria. • **Trelstar**: Palliative treatment of Advanced Prostate Cancer • **Viadur:** Palliative treatment of Advanced Prostate Cancer • **Vantas**: Palliative treatment of Advanced Prostate Cancer • **Zoladex**: Breast Cancer, Endometriosis, Endometrial Thinning, Prostate Cancer	16 years of age
LIPIDS/AMINO ACIDS/PLASMA PROTEINS	Approval will be given if administered in the member's home or in a long-term care facility. If given in the hospital or physician's office, the claim must be billed as a medical expense.	Lifetime
MAKENA Hydroxyprogesterone caproate injection	Makena will be approved for members that meet the following criteria • The drug is being administered in the home or in long-term care setting; • Member has a Singleton pregnancy and a history of singleton spontaneous preterm birth; • Therapy is being initiated between 16 weeks gestation and 20 weeks, 6 days gestation. • Continue through 36 weeks 6 days gestation or delivery; whichever occurs first. • Dose is administered by a healthcare professional.	See criteria
MOXATAG (amoxicillin)	A prior authorization will only be approved if a member is allergic to inactive ingredients in immediate release amoxicillin.	One year
MYALEPT (metreleptin)	Prior Authorization required and will be approved on a case by case basis The Drug Utilization Review (DUR) will be reviewing criteria	
NEWLY APPROVED PRODUCTS	Newly marketed drugs may be subject to prior authorization for a minimum of nine months following FDA marketing approval. Initial approval criteria will include non-preferred criteria (for drugs within a reviewed PDL class); or FDA approved indications, dose, age and place in therapy. For drugs in PDL classes, the next class annual review will include the new agent. For non-PDL drugs, criteria shall be reviewed at the quarterly DUR meeting closest to the nine month minimum.	One year
NORTHERA (droxidopa)	Prior Authorization required and will be approved on a case by case basis The Drug Utilization Review (DUR) will be reviewing criteria	
NUCALA (mepolizumab)	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility. Medications administered in a physician's office must be billed as a medical expense. Because this medication has a Black Box warning requiring the administration under the supervision of a physician, a PA will not be approved if administered in a member's home.	One year
OFEV (Nintedanib)	Ofev will be approved if all the following criteria are met: • Member has been diagnosed with idiopathic pulmonary fibrosis AND	One year

	• Is being prescribed by or in conjunction with a pulmonologist AND • Member is 18 years or older AND • Member has baseline ALT, AST, and bilirubin prior to starting therapy AND • Member does not have moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment AND • Female members of reproductive potential must have been counseled regarding risk to the fetus and to avoid becoming pregnant while receiving treatment with Ofev and to use adequate contraception during treatment and at least 3 months after the last dose of Ofev AND • Member is not taking a P-gp or CYP3A4 inducer (e.g, rifampin, carbamazepine, phenytoin, St. John's Wort) Quantity Limits: 60 tablets/30 days	
OMEGA-3 ETHYL ESTERS	Omega-3-acid ethyl esters will be approved for members that have confirmed diagnosis of hypertriglyceridemia defined as TG ≥ 500 mg/dL	1 year
ONFI (clobazam)	ONFI® will be approved for members who meet the following criteria: • Member is > 2 years of age AND • Has a documented diagnosis of seizure AND • Is being prescribed by or in conjunction with a neurologist AND • Has failed a one month trial with three anticonvulsants (Failure is defined as: lack of efficacy, allergy, intolerable side effects contraindication to, or significant drug-drug interactions).	1 year
OPIOID AGONIST/ANTAGONIST	**Revia (naltrexone)** - A PA is not required. **Naloxone vial or prefilled syringe –** a prior authorization is not required. The atomizer device for use with naloxone can be obtained by the pharmacy billing as a DME claim code A4210. The unit limit is 1 atomizer per vial/syringe dispensed up to a total of 15 per year. A prior authorization is not required. **Bunavail® (buprenorphine/naloxone)** buccal film will be approved for members who meet the following criteria: • Approval will be granted if the prescriber meets the qualification criteria under the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescribe Subutex® or Suboxone® AND • The member has a diagnosis of opioid dependence AND • The member is 16 years of age or older AND • No claims data show concomitant use of opiates in the preceding 30 days unless the physician attests the member is no longer using opioids AND • The member must have tried and failed, intolerant to, or has contraindication to generic buprenorphine/naloxone SL tablets or Suboxone films. **Evzio (naloxone)** is not currently a Medicaid benefit. **Narcan (naloxone)** will be approved if nasal route of administration (via nasal atomizer) cannot be used. **Suboxone (buprenorphine/naloxone)** will be approved if the following criteria are met: • The prescriber is authorized by the manufacturer to prescribe Suboxone • The member has an opioid dependency • The member is not currently receiving an opioid or opioid combination product unless the physician attests the member is no longer using opioids.	One year

	• Will not be approved for the treatment of pain. • Opioid claims will not be allowed for members with a claim for Suboxone in the preceding 30 days. • will not be approved for more than 24mg of buprenorphine /day **Subutex (buprenorphine)** will be approved if all of the following criteria are met: • The prescriber is authorized by the manufacturer to prescribe Subutex • The member has an opioid dependency • The member is pregnant or the member is allergic to Naloxone • Subutex will not be approved for the treatment of pain. • Subutex will not be approved for more than 24mg/day **Vivitrol (naltrexone)** • Approval will be given if administered in the member's home or in a long-term care facility. If given in the hospital or physician's office, the claim must be billed as a medical expense. **Zubsolv (buprenorphine/naloxone)** • Approval will be granted if the prescriber meets the qualification criteria under the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescribe Subutex or Suboxone AND • The member has a diagnosis of opioid dependence AND • The member is 16 years of age or older AND • No claims data show concomitant use of opiates in the preceding 30 days unless the physician attests the member is no longer using opioids AND • The member must have tried and failed, intolerant to, or has a contraindication to generic buprenorphine/naloxone SL tablets or Suboxone films.	
OPIOID MEDICATIONS	**EFFECTIVE 10/1/2017**, the total daily limit of morphine dose equivalent (MED) is decreasing from 300 MED to 250 MED. This includes opioid-containing products where conversion calculations are applied. Prescriptions that cause the member's drug regimen to exceed the maximum daily limit of 250 MED will be denied. • Prior authorizations will be granted to allow for tapering. • Diagnosis of sickle cell anemia will receive a PA for one year. • A one year PA will be granted for admission to or diagnosis of hospice or end of life care. • A one year PA will be granted for pain associated with cancer. Medicaid provides guidance on the treatment of pain, including tapering, on our website HCPF Pain Management Resources • Only one long-acting oral opioid agent (including different strengths) and one short-acting opioid agent (including different strengths) will be considered for a prior authorization. Long-acting opioids are a part of the Preferred Drug List (PDL). Please refer to the PDL posted at https://www.colorado.gov/hcpf/provider-forms for the Preferred Products.	Chronic Pain: 6 months to allow for tapering
OPIOIDS- ORAL SHORT ACTING	**EFFECTIVE 8/1/17,** members who have not filled a prescription for an opioid within the past 365 days will be identified as "opioid treatment naïve" and have the following limitations placed on the initial prescription(s): • The days' supply of the first, second, and third prescription for an opioid will be limited to 7 days, the quantity will be limited to 8 dosage forms per day (tablets, capsules), maximum #56 tablets/capsules for a 7 day supply	Acute pain: one time override per claim

	• The fourth prescription for an opioid will require prior authorization, filling further opioid prescriptions may require a provider to provider telephone consultation with the pain management physician provided by Medicaid at no charge to provider or member • If a member has had an opioid prescription filled within the past 365 days, then this policy would not apply to that member and other opioid policies would apply as applicable. • **Short acting opioids** will be limited to a total of 120 tablets per 30 days (4/day) per member for members who not included in the opioid treatment naive policy. Exceptions will be made for members with a diagnosis of a terminal illness (hospice or palliative care) or sickle cell anemia. For members who are receiving more than 120 tablets currently and who do not have a qualifying exemption diagnosis, a 6-month prior authorization can be granted via the prior authorization process for providers to taper members. Please note that if more than one agent is used, the combined total utilization may not exceed 120 units in 30 days. There may be allowed certain exceptions to this limit for acute situations (for example: post-operative surgery, fractures, shingles, car accident). Information regarding tapering, morphine equivalents, other therapies and other resources can be found on the Department website at: https://www.colorado.gov/pacific/hcpf/pain-management-resources-and-opioid-use	
ORACEA (doxycycline)	A prior authorization will only be approved if all of the following criteria are met: • member has taken generic doxycycline for a minimum of three months and failed therapy in the last 6 months (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions), • member has been diagnosed with rosacea with inflammatory lesions, and member is 18 years of age or older	16 weeks
ORKAMBI (lumacaftor/ivacaftor)	**ORKAMBI®** will be approved for members if the following criteria has been met: • Member must have diagnosis of cystic fibrosis with genetic testing performed to confirm that member is homozygous for the F508del mutation in the CFTR gene AND • Member is 6 years of age or older AND • Member is being treated by a pulmonologist AND • Member has < 5 times upper limit of normal (ULN) AST/ALT or < 3 times ULN AST/ALT if concurrently has > 2 times ULN bilirubin at time of initiation AND • Member has serum transaminase and bilirubin measured before initiation and every 3 months during the first year of treatment	One year
OTC PRODUCTS	Medical Necessity • Aspirin, Insulin and Plan B are covered without a PA • Prilosec OTC: *See Proton Pump Inhibitor's section* • Guaifenesin 600mg LA is covered for members having an abnormal amount of sputum • Quinine Sulfate *is no longer covered* for leg cramps • Herbal products are not a benefit except for cranberry tablets, which are covered for urinary tract infections • Diabetic needles and supplies are not a prescription benefit and should be billed as supply • Broncho saline is not covered- refer to Sodium Chloride section • Cough and Cold Products must have a diagnosis of a chronic respiratory condition for which these medications may be prescribed or otherwise be medically necessary	One year

<table>
<tr><td></td><td>• Antihistamine (w/ decongestant) must have a diagnosis of seasonal or perennial allergic rhinitis or chronic sinusitis or otherwise be medically necessary
• Nicomide is approved for acne
Nursing Facilities: Please provide OTC floor stock list.
Members with Erythema Bullosum (EB) can receive any OTC medication with a prior authorization.</td><td></td></tr>
<tr><td>OTREXUP (methotrexate)</td><td>METHOTREXATE AUTOINJECTOR authorization will be approved for members who meet the following criteria:
• Member has diagnosis for rheumatoid arthritis AND
• Member cannot take methotrexate by mouth due to intolerable gastrointestinal side effects AND
• Member cannot take an injection due to limited functional ability.</td><td>One year</td></tr>
<tr><td>OXSORALEN (methoxsalen)</td><td>Approval will be granted with diagnosis of: Myosis; Fungoides; Psoriasis or Vitiligo</td><td>One year</td></tr>
<tr><td>PCSK9 INHIBITORS</td><td>PCSK9 injections will be approved for members that meet the following criteria:
• Member has the below diagnosis for each agent below:
o Praluent: heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease
o Repatha: heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease AND
• PCSK9 is prescribed by one of the following providers: AND
o Cardiologist
o Lipid Specialist
o Endocrinologist AND
• Member is concurrently adherent (>80% of the past 180 days) on maximum doses (see table below) of statin therapy (must include atorvastatin and rosuvastatin). If member is intolerant to statins due to side effects, must have documented three-month trial and failure of pravastatin and one other statin at lower doses and/or every other day treatment. For members with a past or current incidence of rhabdomyolysis, three-month failure is <u>not</u> required AND
<table><tr><td>Atorvastatin 80mg</td></tr><tr><td>Fluvastatin 80 mg</td></tr><tr><td>Lovastatin 80 mg</td></tr><tr><td>Pravastatin 80 mg</td></tr><tr><td>Rosuvastatin 40 mg</td></tr><tr><td>Simvastatin 40 mg (80 mg not used in practice)</td></tr></table>• The member has <u>not</u> achieved 50% reduction in LDL-C from baseline while > 80% adherent for the past 180 days on maximally tolerated statin, diet and adjunct lipid lowering therapies AND
• Prescribing provider attests to providing appropriate counseling to advise a diet with sufficient fruits and vegetables, fiber, and omega-3 fatty acids AND
• Member must be concurrently treated (in addition to statin) with one of the following unless contraindicated or significant safety concern exists: ezetimibe, niacin, and bile acid sequestrate AND
• LDL-C levels must be > 250 AND
• PA will be granted for 12 weeks initially, and LDL-C will be required after 8 weeks of treatment for dose optimization. A reduction in LDL-C of at least 45 % since initiation of treatment with PCSK9 is required to continue therapy.</td><td>Max - One year</td></tr>
</table>

PHENOBARBITAL	For Medicaid primary members, barbiturates (phenobarbital) will be approved for use in epilepsy, cancer, chronic mental health disorder, sedation, treatment of insomnia, tension headache, muscle contraction headache and treatment of raised intracranial pressure. All other uses will require manual review. Phenobarbital will be approved for neonatal narcotic abstinence syndrome based on the following criteria: • The member has a diagnosis of non-opiate or polysubstance abuse **OR** • The member has first failed methadone for the diagnosis of opiate withdrawal **AND** • Serum phenobarbital levels are being monitored. Max duration: 3 months	Max 3 months for neonatal abstinence 1 year otherwise
PHYSICIAN ADMINISTERED DRUGS	Medications given in a hospital, doctor's office or dialysis unit are only to be billed directly by those facilities as a medical item. IV Fluids, meds, etc. may be billed by the pharmacy when given in a long-term care facility or by home infusion following prior authorization approval. Prior authorizations will be approved based upon documentation of the location for administration.	
PROCYSBI (cysteamine)	Approval will be granted if the member is 2 years of age or older **AND** Has a diagnosis of nephropathic cystinosis **AND** documentation is provided to the Department that treatment with cysteamine IR (Cystagon®) was ineffective, not tolerated, or is contraindicated.	One year

PROMACTA (eltrombopag)	Promacta will be approved for members with **Chronic Immune Thrombocytopenia Purpura (ITP)** if the following criteria is met:
	
	• Confirmed diagnosis of chronic (> 3 months) immune idiopathic thrombocytopenia purpura AND
	• Must be prescribed by a hematologist AND
	• Member is at risk (documented) of spontaneous bleed as demonstrated by the following labs: AND
	  o Platelet count less than 20,000/mm3 or
	  o Platelet count less than 30,000/mm3 accompanied by signs and symptoms of bleeding
	• In the past 6 months, member has tried and failed (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) systemic corticosteroids (e.g. prednisone 1 to 2 mg/kg for 2 to 4 weeks, or pulse dexamethasone 40 mg daily for 4 days), immunoglobulin replacement, or splenectomy.
	Promacta will be approved for members with **Thrombocytopenia associated with Hepatitis C** if the following criteria is met:
	
	• Member must have confirmed diagnosis of chronic hepatitis C associated thrombocytopenia AND
	• Must be prescribed by a gastroenterologist, infectious disease specialist, transplant specialist or hematologist AND
	• Member has clinically documented thrombocytopenia defined as platelets < 60,000 microL AND
	• Patients' degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy
	Promacta will be approved for members with **Severe Aplastic Anemia** if the following criteria is met:
	
	• Member must have confirmed diagnosis of Severe Aplastic Anemia AND
		One year

	• Must be prescribed by a hematologist AND • Member must have had a documented insufficient response to immunosuppressive therapy (antithymocyte globulin (ATG) alone or in combination with cyclosporine and/or a corticosteroid *Prior authorizations will be granted for 12 months. Further approvals for a maximum of 6 months require lab results and documentation for efficacy.	
PROMETHAZINE	A Prior authorization is required for all routes of administration for members under the age of two. Children under the age of two should not use Promethazine. Promethazine is contraindicated in such patients because of the potential for fatal respiratory depression. Not qualified for emergency 3 day supply PA	One year
PROPECIA (finasteride)	***Not covered for hair loss*** *Not qualified for emergency 3 day supply PA*	One year
PULMOZYME (dornase alfa)	Pulmozyme will be approved for members that meet the following criteria: • Member has a diagnosis of cystic fibrosis AND • Member is five years of age or older o For children < 5 years of age, Pulmozyme will be approved if the member has severe lung disease as documented by bronchoscopy or CT scan Pulmozyme twice daily will only be approved if patient has tried and failed an adequate trial of once daily dosing for one month All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon documentation from the prescriber that the member continues to benefit from Pulmozyme therapy. Quantity Limits: 30 ampules (2.5 mg/2.5 ml) per month	
RASUVO (methotrexate) Auto-Injector	Rasuvo will be approved for members who meet the following criteria: • Member has diagnosis for rheumatoid arthritis AND • Member cannot take methotrexate by mouth due to intolerable gastrointestinal side effects AND • Member cannot take a methotrexate injection via syringe due to limited functional ability	One year
RAVICTI (glycerol phenylbutyrate)	Ravicti will only be approved for members meeting the following criteria: • Member must be 2 years of age or older • Member must have a documented diagnosis of urea cycle disorder (UCD) • Member must be on a dietary protein restriction (verified by supporting documentation) • Member must have tried and failed Buphenyl as evidenced by uncontrolled hyperammonia over the past 365 days • Medication must be prescribed by a physician experienced in the management of UCD (e.g., geneticist)	One year
REBATE DISPUTE DRUGS	Medical necessity. Not qualified for emergency 3 day supply PA	One year

REQUIP XL (pramipexole)	A prior authorization will only be approved if a member has tried and failed on generic immediate release ropinirole for a period of 3 or more months in the last 6 months and the member has a diagnosis of Parkinson's disease. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) **Grandfathering:** Members who have been previously stabilized on Requip XL can receive approval to continue on the medication for one year if medically necessary.	One year
SANDOSTATIN (octreotide)	Approved for: acromegaly; carcinoid tumors; and vasoactive intestinal peptide tumors.	Lifetime
SILENOR (doxepin)	A prior authorization will be approved if a member meets one of the following criteria: • Contraindication to preferred oral sedative hypnotics (Lunesta, zaleplon and zolpidem) • Medical necessity for doxepin dose < 10 mg • Age greater than 65 years old or hepatic impairment (3 mg dose will be approved if this criteria is met)	One year
SIMVASTATIN 80mg	Simvastatin 80mg dose products will only be covered for members who have been stable for more than 12 months at that dose. Providers should consider alternate preferred statins in members who have not met cholesterol goals on simvastatin at doses up to 40mg per day. Please refer to the FDA communication entitled, "FDA Drug Safety Communication: New restrictions, contraindications, and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury" for updated guidance on contraindications, dose limits and relative LDL lowering doses of alternatives.	One year
SODIUM CHLORIDE For inhalation use	Broncho Saline is **not** covered as a drug benefit. Inhaled NaCl is now classified as a supply and can only be billed as medical. All requests for sodium chloride (inhalation use) must be billed through medical.	N/A
SOLARAZE 3% GEL (diclofenac sodium)	A prior authorization will only be approved if the member has a diagnosis of Actinic Keratoses (AK).	One year
STADOL (butorphanol) nasal spray	Quantity limit: 10mg/ml 2.5ml bottle limit of 4 bottles (10ml) per 30 days	One year
STRENSIQ® (asfotase alfa)	Prior Authorization required and will be approved on a case by case basis The Drug Utilization Review (DUR) will be reviewing criteria	
SYNAGIS (Palivizumab)	**Pharmacy Prior Authorization requests for Synagis® must be submitted by fax or phone using the Synagis® Prior Authorization Form found at** https://www.colorado.gov/hcpf/provider-forms. **Medical PAs must be submitted through eQHealth at** http://coloradopar.com/. **Synagis® season will begin November 27, 2017 and end April 30, 2018. PARs may be requested beginning November 16, 2017.** **Key Points** 1. No more than 5 doses per season. 5 doses provide more than 6 months of protective serum concentration. 2. Synagis® is not recommended for controlling outbreaks of health care-associated disease. 3. Synagis® is not recommend for prevention of health care-associated RSV disease. 4. Infants born later in the season may require less than 5 doses to complete therapy to the end of the season. 5. Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.	Maximum of 5 doses per season

	6. Synagis® is not recommended to prevent wheezing, nosocomial disease, or treatment of RSV 7. Synagis® is not routinely recommended for patients with a diagnosis of Down syndrome unless they also have a qualifying indication listed below. 8. In the **first year of life** Synagis® is recommended: a. For infants born before 29w 0d gestation. b. For infants born before 32w 0d **AND** with CLD of prematurity **AND** requirements of >21% oxygen for at least 28 days after birth. c. For infants with hemodynamically significant heart disease (acyanotic heart disease who are receiving medication to control CHF and will require cardiac surgical procedures **AND** infants with moderate to severe pulmonary hypertension**) AND** born within 12 months of onset of the RSV season. d. Children who undergo cardiac transplantation during the RSV season. e. For infants with cyanotic heart defects AND in consultation with a pediatric cardiologist AND requirements of >21% oxygen for at least 28 days after birth AND continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) f. If an infant has neuromuscular disease or pulmonary abnormality AND is unable to clear secretions from the upper airways g. A child who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy) h. An infant with cystic fibrosis with clinical evidence of CLD AND/OR nutritional compromise 9. In the **second year of life** Synagis® is recommended for: a. Infants born before 32w 0d **AND** with CLD of prematurity **AND** requirements of >21% oxygen for at least 28 days after birth **AND** continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) b. A child who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy) c. Infants with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities of chest radiography or chest computed tomography that persist when stable) **OR** weight for length less than the 10th percentile. d. Children who undergo cardiac transplantation during the RSV season.	
SYPRINE (Trientine)	Prior Authorization required and will be approved on a case by case basis The Drug Utilization Review (DUR) will be reviewing criteria	
TARGETED IMMUNE MODULATORS (iv infused products)	Entyvio (vedolizumab): • Entyvio will be approved for adult members with ulcerative colitis or Chrohn's Disease AND • For Diagnosis of Crohn's Disease, have trialed and failed Humira and Cimzia OR • For Diagnosis of Ulcerative Colitis, have trialed and failed Humira and Simponi AND o Failure is defined as (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) • Has had an inadequate response with, intolerance to, or demonstrated a dependence on corticosteroids AND • Will be receiving Entyvio in a home health or long-term care setting AND • Member is not receiving Entyvio in combination with Humira, Simponi, or Tysabri AND • Entyvio Is initiated and titrated per FDA labeled dosing for Crohn's Disease and Ulcerative Colitis up to a maximum of 300mg IV infusion every 8 weeks	One year

	Orencia (abatacept) – will be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following: • Members with moderate to severe rheumatoid arthritis who have failed therapy with both Enbrel and Humira • Members with moderate to severe juvenile idiopathic arthritis Remicade (infliximab) will be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following: • members with ulcerative colitis • members with rheumatoid arthritis who have tried and failed therapy with both Enbrel and Humira • members with psoriatic arthritis • members with ankylosing spondylitis • members with juvenile idiopathic arthritis • members with plaque psoriasis • members with Crohn's Disease Rituxan (rituximab) - will be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following: • Members with moderate to severe rheumatoid arthritis who have tried and failed both Enbrel and Humira • Members with Chronic Lymphocytic Leukemia • Members with Non-Hodgkins Lymphoma	
THROMBOLYTIC ENZYMES	Approved for **IV Catheter Clearance or Occluded AV Cannula** if given in member's home or long term care facility.	One year
TOBACCO CESSATION (Rx & OTC)	Prior authorization is required for all tobacco cessation medications except for the first fill of the gum/lozenge form of short-acting nicotine replacement therapy (NRT). Members can receive combination therapy with patch form of long-acting NRT and gum/lozenge short-acting NRT per 90 day benefit. Members should be referred to the QuitLine or another behavior modification program. The name of that program should be included on the prior authorization form. Medical Assistance Program will pay for multiple strengths of a product (patch, gum, or lozenge) or multiple products during the two 90-day paid benefit periods.	Two 90-day paid benefits per year Not qualified for emergency 3 day supply PA
TORADOL (ketorolac)	**Quantity limit:** 5 days of therapy for every 30 days = 20 tablets per 30 days	
TPN PRODUCTS	Approval will be given if administered in the member's home or in a long-term care facility. If given in the hospital or physician's office, the claim must be billed as a medical expense.	Lifetime
TRAMADOL	Tramadol products will be approved if the following criteria are met: • Member is 12 years of age or older AND • If member is less than 18 years of age, tramadol is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND • If member is between 12 and 18 years of age, member is not obese (BMI greater than 30kg/m^2), have obstructive sleep apnea, or severe lung disease Tramadol is not approved for more than 400mg/day. **Rybix ODT** Rybix will be approved for members who are unable to swallow oral tablets or for members who are unable to absorb oral medications (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year

<table>
<tr><td></td><td>Ryzolt
A prior authorization will only be approved if a member has tried and failed on the maximum dose of tramadol (400mg per day) for a period of 3 or more months in the last six months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)</td><td></td></tr>
<tr><td>TYBOST (Cobicistat)</td><td>TYBOST® will be approved for members who meet the following criteria:
• Member has a diagnosis of HIV-1 AND
• Member is currently being treated with atazanavir or darunavir only AND
• Member is not taking cobicistat-containing drugs, or ritonavir-containing drugs AND
• Member has failed treatment with ritonavir (failure defined as intolerable side effect, allergy, or lack of efficacy).</td><td>One year</td></tr>
<tr><td>VACCINES</td><td>All other vaccines must be bill on Colorado 1500 form as a medical expense unless administered in long-term care facility. Any vaccine can be approved by prior authorization if a member is living in a long-term care facility. (Not a covered benefit for regular patients – only long-term care facilities).

Not qualified for emergency 3 day supply PA</td><td>One year</td></tr>
<tr><td>VALCYTE (valgancyclovir hydrochloride)</td><td>Valcyte will be approved for members with diagnosis of Cytomegalovirus (CMV) retinitis AND acquired immunodeficiency Syndrome (AIDS) per dosing guidelines below
OR
For members that require prophylactic treatment for CMV post kidney, heart or kidney-pancreas transplant per dosing guidelines below
OR
For members ≤ 16 years of age that are at high risk of CMV infection and need prophylactic treatment post heart or kidney transplant per dosing guidelines below

<table>
<tr><th colspan="2">Adult Dosage</th></tr>
<tr><td>Treatment of CMV retinitis</td><td>Induction: 900 mg (two 250 mg tablets) twice a day for 21 days
Maintenance: 900 mg once a day</td></tr>
<tr><td>Prevention of CMV disease in heart or kidney-pancreas patients</td><td>900 mg once a day within 10 days of transplantation 100 days post-transplantation</td></tr>
<tr><td>Prevention of CMV disease in kidney transplant patients</td><td>900 mg once a day within 10 days of transplantation until 200 days post-transplantation</td></tr>
<tr><th colspan="2">Pediatric Dosage</th></tr>
<tr><td>Prevention of CMV disease in kidney transplant patients 4 month to 16 years of age</td><td>Dose once daily within 10 days of transplantation until 200 days post-transplantation</td></tr>
<tr><td>Prevention of CMV disease in heart transplant patients 1 month to 16 years of age</td><td>Dose once a day within 10 days of transplantation until 100 days post-transplantation</td></tr>
</table></td><td>One year</td></tr>
<tr><td>VELTASSA (patiromer)</td><td>A prior authorization will be approved for members that meet the following criteria:
• Documented diagnosis of hyperkalemia (serum potassium > 5 mEq/L) AND
• Veltassa is not being used for emergent hyperkalemia AND
• Member does not have severe gastroinstestinal motility dysfunction AND</td><td>One year</td></tr>
</table>

	• Member does not have hypomagnesemia (serum magnesium < 1.4 mg/dL)	
VERIPRED (prednisolone)	A prior authorization will only be approved if a member has tried and failed on a generic prednisolone product (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions.)	One year
VERSED (Midazolam)	Approved if given in the member's home or in a long-term care facility and given for: • Preoperative sedation or anesthesia • Terminally ill members with Cancer • Member with Erythema Bullosum (EB) –approval for one year	One month
VERSED Midazolam injection used as nasal spray	Midazolam injection used as a nasal inhalation will be approved for members who meet the following criteria: • Member is ≥ 6 months of age AND • Has a diagnosis of seizure disorder AND • Is prescribed by or in conjunction with a Neurologist AND • Treatment dose does not exceed 10mg Dosing Limits: 10 vials or prefilled syringes/month Only MIDAZOLAM 5mg/ml (for doses ≤ 5mg) and 10mg/2ml (for doses > 5 mg) will be covered. The atomizer device for use with midazolam can be obtained by the pharmacy billing as a DME claim code A4210. The atomizer dispensed limit is up to a total of 15 per year. A prior authorization is not required.	One year
VIMOVO (naproxen/esomeprazole magnesium)	Approved if member has failed treatment with two Preferred Proton Pump Inhibitors within the last 24 months, and has one of the following diagnoses: • Ankylosing spondylitis in patients at increased risk of developing NSAID induced ulcers; • Osteoarthritis in patients at increased risk of developing NSAID induced ulcers; • Rheumatoid arthritis in patients at increased risk of developing NSAID induced ulcers.	One year
VITAMINS (Rx)	**Prescription Vitamins (except for prenatals) will be authorized for:** • ESRD, CRF, renal insufficiency, diabetic neuropathy or renal transplant • Members under the age of 21 with a diagnosis disease that prohibits the nutrition absorption process as a secondary effect of the disease. • Members with Erythema Bullosum (EB) Hydroxocobalamin Injections In addition to the above general vitamin criteria, approval can also be given for methylmalonic academia (MMA). Cyanocobalamin Injections In addition to the above general vitamin criteria, approval can also be given for vitamin B12 deficiency. Folic Acid Vitamins (exceptions exist for Folic Acid 1mg, see below) In addition to the above general vitamin criteria, approval can also be given for folic acid vitamins if one of the following criteria is met: • Currently taking Methotrexate or Alimta • A diagnosis of folic acid deficiency (megaloblastic and macrocytic anemia are the most common). Some drugs or other conditions may cause deficiency -- Approval will be granted for these indications IF the member has current folic acid deficiency and documented by the provider. • For Female Members: Approval will be granted for the prevention of a neural tube defect pregnancy and for the prevention of miscarriages.	One year

	• Homocysteinemia • Sickle cell disease Cyanocobalamin/Folic Acid/Pyridoxine In addition to the above general vitamin criteria, approval can also be given for members: • with Homocysteinemia or Homocystinuria • on dialysis • with or at risk for cardiovascular disease **L-methylfolate** approved for depressed members who are currently taking antidepressants and are partial or non-responders **Metanx** approved for members with non-healing diabetic wounds **Prenatal Vitamins** are a regular benefit for all female members. Prenatal vitamins are not covered for male members. **Folic Acid 1mg** does not require a prior authorization for female members. **Prescription Vitamin D and Vitamin K products** do not require a prior authorization.	
VUSION OINTMENT (miconazole/zinc oxide/white petrolatum)	A prior authorization will only be approved if a member has failed on an OTC antifungal **and** a generic prescription antifungal. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year
XERESE (acyclovir/hydrocortisone)	A prior authorization will be approved for members that meet the following criteria: • Documented diagnosis of recurrent herpes labialis AND • Member is immunocompetent AND • Member has failed treatment of at least 10 days with acyclovir (please refer to the Anti-Herpetic Agents segment of the PDL for dose recommendations). Failure will be defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects) AND • Member has failed treatment of at least one day with famciclovir 1500 mg OR valacyclovir 2 GM twice daily (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects)	One year
XOLAIR (omalizumab)	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility. Medications administered in a physician's office must be billed as a medical expense. Because this medication has a Black Box warning requiring the administration under the supervision of a physician, a PA will not be approved if administered in a member's home.	One year
XYREM (sodium oxybate)	XYREM may be approved for adults if all the following criteria are met: • Member has a diagnosis of narcolepsy with excessive daytime sleepiness or cataplexy AND • Member must not have recent (within 1 year) history of substance abuse AND • Member is not taking opioids, benzodiazepines, alcohol, or sedative hypnotics (zolpidem, zaleplon, eszopiclone, chloral hydrate) concomitantly with Xyrem AND • Member has a history of failure, contraindication, or intolerance for sleep induction/maintenance including zolpidem, zaleplon, eszopiclone, and temazepam AND	One year

	• Member has trialed preferred psychostimulants for narcolepsy including Adderall, methylphenidate, and dexmethylphenidate AND • Prescriber is enrolled in Xyrem REMS program • Maximum dose 9g/day	
YOSPRALA (aspirin/omeprazole) Delayed release tablets	Yosprala will be approved for members who meet the following criteria: • Member requires aspirin for secondary prevention of cardiovascular or cerebrovascular events AND • Member is at risk of developing aspirin associated gastric ulcers (member is ≥ 55 years of age or has documented history of gastric ulcers) AND • Member has failed treatment with three preferred proton pump inhibitors in the last 6 months (Failure is defined as: lack of efficacy of a seven-day trial, allergy, intolerable side effects, or significant drug-drug interaction.)	One year